Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH), (http://www.nih.gov)

Components of Participating Organizations
National Institute of Nursing Research (NINR) (http://www.ninr.nih.gov)
National Heart, Lung and Blood Institute (NHLBI) (www.nhlbi.nih.gov)
National Cancer Institute (NCI) (http://www.nci.nih.gov)
Office of Behavioral and Social Sciences Research (OBSSR) (http://obssr.od.nih.gov)

Title: Health Promotion Among Racial and Ethnic Minority Males (R21)

Announcement Type
This Funding Opportunity Announcement (FOA) is a reissue of PA-07-421.

Updates: The following updates relating to this announcement have been issued:

- August 16, 2010 - IMPORTANT NOTE! NIH has eliminated the error correction window for due dates of January 25, 2011 and beyond. As of January 25, all corrections must be complete by the due date for an application to be considered on-time. See NOT-OD-10-123.
- September 29, 2010 (NOT-OD-11-007) - NIH to Require Use of Updated Electronic Application Forms in 2011. Adobe B1 forms are required for due dates on or after May 8, 2011.

Program Announcement (PA) Number: PA-10-237

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (http://www.grants.gov) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission date. See Section IV.

Apply for Grant Electronically

A compatible version of Adobe Reader is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at http://grants.gov/CustomerSupport.

Catalog of Federal Domestic Assistance Number(s)
93.361, 93.837, 93.399

Key Dates
Release/Posted Date: July 22, 2010

Opening Date: September 16, 2010 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date(s): Not Applicable
NOTE: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).
Application Due Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm
AIDS Application Due Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS.
Peer Review Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Council Review Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Earliest Anticipated Start Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Additional Information To Be Available Date (URL Activation Date): Not Applicable
Expiration Date: September 8, 2013

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** This Funding Opportunity Announcement (FOA) encourages Exploratory/Developmental (R21) grant applications from applicants that propose to stimulate and expand research in the health of minority men. Specifically, this initiative is intended to: 1) enhance our understanding of the numerous factors (e.g., sociodemographic, community, societal, personal) influencing the health promoting behaviors of racial and ethnic minority males and their subpopulations across the life cycle, and 2) encourage applications focusing on the development and testing of culturally and linguistically appropriate health-promoting interventions designed to reduce health disparities among racially and ethnically diverse males and their subpopulations age 21 and older.
- **Mechanism of Support.** This FOA will use the NIH Exploratory/Developmental (R21) award mechanism and runs in parallel with a FOA of identical scientific scope, PA-10-236 , that encourages applications under the R01 mechanism.
- **Funds Available and Anticipated Number of Awards.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the mechanism numbers, quality, duration, and costs of the applications received.
- **Budget and Project Period.** The total project period for an application submitted in response to this funding opportunity may not exceed two years. Direct costs are limited to $275,000 over an R21 two-year period, with no more than $200,000 in direct costs allowed in any single year.
- **Application Research Strategy Length:** The R21 Research Strategy section may not exceed 6 pages, including tables, graphs, figures, diagrams, and charts. See. See Table of Page Limits
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application.
- **Number of Applications.** Applicants may submit more than one application, provided that each

application is scientifically distinct.

- **Resubmissions.** Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). See new NIH policy on resubmission (amended) applications (NOT-OD-09-003, NOT-OD-09-016).
- **Renewals.** Exploratory/developmental grant support is for new projects only; competing renewal (formerly "competing continuation") applications will not be accepted.
- **Special Date(s).** This FOA uses non-standard due dates. See Receipt, Review and Anticipated Start Dates
- **Application Materials.** See Section IV.1 for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
  - SF424 (R&R) Application and Electronic Submission Information: http://grants.nih.gov/grants/funding/424/index.htm
  - General information on Electronic Submission of Grant Applications: http://era.nih.gov/ElectronicReceipt/
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

Table of Contents

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

It is well documented that males experience approximately a five-year shorter life expectancy when compared with females. During the 20th century, life expectancy at birth increased from 48 to 74 years for males and from 51 to 79 years for females. Increases in life expectancy are, in part, attributed to improvements in lifestyle, nutrition, housing, hygiene and medical care. The disparities in life expectancy are more pronounced among men of color and economically disadvantaged males. For example, the life expectancy of

European American males and African American males are 74.6 and 67.7 years respectively.

In 2005, the National Center for Health Statistics reported the leading causes of death in males as heart disease, cancer (lung and prostate), accidents unintentional injuries, stroke, lung disease, diabetes, pneumonia, influenza, suicide, chronic liver disease, and Alzheimers disease. Mortality rates from these causes of death are higher for minority males because their diseases are at a more advanced stage at diagnosis and are often complicated by co-existing conditions.

To illustrate, while cardiovascular disease is the leading cause of death for all Americans, white males have the greatest mortality from cardiovascular disease, 39.2% of all deaths, followed by 36.1% of all deaths for Asian American and Pacific Islander males, and 34.2% of all deaths for African American males. While Hispanic males experience the lowest death rate from cardiovascular disease, 27.9%, they suffer disproportionately from other conditions related to heart disease namely hypertension, high cholesterol and diabetes. African American males experience an earlier onset of the disease and experience a higher rate of complications. Cardiovascular disease mortality rates in African American males ages 35-64 are more than twice those of Caucasian males. One out of six African American men, ages 30-39, has hypertension, and by age 50-59, almost 60% are hypertensive. African American men also have low hypertension control rates and higher risk of fatality from stroke when compared to their White counterparts.

Other examples of health disparities noted among minority males include the following:

- The prevalence of extreme obesity in African American men is higher than in any other minority group. Among African American men, the prevalence of obesity increased from 27.5% in 1999-2000 to 31% in 2003-2004. Poor dietary patterns together with physical inactivity are highly prevalent in minority males

and are major contributors to the high obesity prevalence rates.
- HIV infection is the third leading cause of death for Hispanic males ages 25-44, and the second leading cause of death in African American males within the same age group.
- Diabetes affects all racial and ethnic populations, but American Indians have the highest rate of diabetes in the world.

Many of the disparities in health status noted among racial and ethnically diverse male populations are related to lifestyle and are either preventable or amenable to early detection or intervention. For example, tobacco use constitutes the single most preventable cause of premature death in the US. In 2004, an estimated 44.5 million adults in the United States were smokers - 23.4% of men and 18.5% of women. Cigarette smoking was highest among male Alaska Natives (33.4%), followed by African Americans (23.9%), Hispanics (18.9%), and Asian/Pacific Islanders (17.8%).

Similarly, many unintentional injuries are preventable and can be prevented

if intervention is instituted early. According to epidemiologists, Over 400 Americans die each day from unintentional injuries such as motor vehicle crashes, poisonings, drowning, falls, fires, suffocation, and firearms. A major objective outlined by Healthy People 2010 is to reduce deaths from unintentional injuries from baseline 35.0 deaths per 100,000 populations to 17.5 deaths per 100,000 populations.

Males are more likely than females to experience death from unintentional injury. Minority males are more at risk to die from such injuries when compared with their White counterparts. For example, in 2004 the death rate for unintentional injuries is 51.6 per 1000,000 deaths (year) for white males. The death rate for unintentional injuries is 51.6 per 100,000 deaths for White males. This compares with 72.5 deaths per 100,000 for American Indian/Alaska Native males followed by 55.6 per 100,000 deaths for African American males and 44.7 per 100,000 deaths for Hispanic males. The disparities in health are often more pronounced among underserved and uninsured racial and ethnic minority males who often delay in seeking clinical care. There are ample data highlighting that uninsured individuals experience greater declines in health status and die prematurely from a variety of illnesses when compared to those with continuous health care coverage. This is particularly important given that racial and ethnic minority populations are disproportionately represented among the uninsured. For example, in 2005, 23% of African American males were uninsured followed by 30.7% of Hispanic males. This compares with 11.2% White males. These and other health disparities noted among minority males require greater elucidation and intervention.

The focus of this FOA is on health promotion among racial and ethnic minority men. A scientific exploration of these disparities is central to NIHs commitment to reducing health disparities. Research in this area is essential to addressing Goal 2 outlined in Healthy People 2010: "To eliminate health disparities among segments of the population, including differences that occur by gender, race or ethnicity, education or income, disability, geographic location or sexual orientation." Generally, men access primary care facilities less often than women and are thus more inclined to delay accessing diagnostic services and treatments. Thus interventions in this area of study need to be innovative and cognizant of these patterns.

The following are potential areas of research related to this announcement. These suggested areas of research are not listed in any priority and are not to be viewed as an exhaustive or exclusive list. Investigators responding to this announcement may target other groups of minority males (e.g., men of diverse sexual orientation, migrant workers, disabled men, rural and immigrant men).

Potential research topics include but are not limited to:

- Studies that test innovative interventions to reduce risk factors associated with the leading causes of morbidity and mortality (e.g., smoking, poor nutrition, alcohol use, sedentary lifestyle, risky sexual behavior) among racial and ethnic minority men and their subpopulations in rural, urban, and nontraditional settings, including interventions addressing multiple risk factors in the same individual.
- Multifaceted interventions designed to increase both initial and repeat health screenings and risk

assessment among racial and ethnic minority and underserved men.

- Research to understand and promote informed decision making among minority males about the PSA test to screen for prostate cancer. Questions may include: How do attitudes towards informed decision making in health care influence men's use of the PSA test? What factors (interpersonal, community, individual) influence men in their decisions to have the PSA test to screen for prostate cancer?
- Studies that include innovative approaches involving families, social networks, or communities in interventions designed to enhance health-promotion structures and behaviors.
- Unique interventions developed to promote positive physical and mental health seeking and health maintenance behaviors among diverse groups of men examining pathways between childhood and adult health.
- Interventions that incorporate faith, cultural and family values and are designed to test the effects of unique and creative intergenerational health promotion activities.
- Interventions that target two or more high-risk behaviors in a single application, e.g., tobacco use, risky sexual behaviors, unintentional (accidents) and intentional behaviors (firearm related injuries.)
- Culturally and linguistically appropriate studies designed to enhance self-efficacy, competence, and skill development to support the initiation and maintenance of health promoting behaviors.
- Studies that develop and test strategies to increase the use of best practices in men's health, such as evidence based guidelines or research syntheses, in health care settings.
- Studies that include innovative biopsychosocial and biobehavioral approaches.
- Studies on the perceptions of masculinity over the life course including coping behavior resulting from masculinity stress and within race, ethnic differences and perceptions of masculinity.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

1. Mechanism of Support

This FOA will use the NIH Exploratory/Developmental Research Grant (R21) award mechanism. The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses "Just-in-Time" information concepts see SF424 (R&R) Application Guide). It also uses modular as well as non-modular budget formats (see the "Modular Applications and Awards" section of the *NIH Grants Policy Statement*. Specifically, if you are submitting an application with direct costs in each year of $250,000 or less (excluding consortium Facilities and Administrative [F&A] costs), use the PHS398 Modular Budget component provided in the SF424 (R&R) Application Package and SF424 (R&R) Application Guide (see specifically Section 5.4, "Modular Budget Component," of the Application Guide).

U.S. applicants requesting more than $250,000 in annual direct costs and all foreign applicants must complete and submit budget requests using the Research & Related Budget component.

2. Funds Available

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the Institutes and Centers (ICs) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

The total project period for an application submitted in response to this funding opportunity may not exceed 2 years. Although the size of award may vary with the scope of research proposed, it is expected that applications will stay within the budgetary guidelines for an exploratory/developmental project; direct costs are

limited to $275,000 over an R21 two-year period, with no more than $200,000 in direct costs allowed in any single year. Applicants may request direct costs in $25,000 modules, up to the total direct costs limitation of $275,000 for the combined two-year award period. NIH grants policies as described in the *NIH Grants Policy Statement* will apply to the applications submitted and awards made in response to this FOA.

Facilities and Administrative (F&A) costs requested by consortium participants are not included in the direct cost limitation, see NOT-OD-05-004.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Small Businesses
- For-Profit Organizations (Other than Small Businesses)
- State Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribally Designated Organizations
- County Governments
- City or Township Governments
- Special District Governments
- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- U.S. Territory or Possession
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations)
- Other(s):
    - Eligible Agencies of the Federal Government
    - Faith-based or Community-based Organizations.

1.B. Eligible Individuals

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

More than one PD/PI (i.e., multiple PDs/PIs), may be designated on the application for projects that require a “team science” approach and therefore clearly do not fit the single-PD/PI model. Additional information on the implementation plans and policies and procedures to formally allow more than one PD/PI on individual

research projects is available at http://grants.nih.gov/grants/multi_pi. All PDs/PIs must be registered in the NIH electronic Research Administration (eRA) Commons prior to the submission of the application (see http://era.nih.gov/ElectronicReceipt/preparing.htm for instructions).

The decision of whether to apply for a grant with a single PD/PI or multiple PDs/PIs is the responsibility of the investigators and applicant organizations and should be determined by the scientific goals of the project. Applications for grants with multiple PDs/PIs will require additional information, as outlined in the instructions below. When considering the multiple PD/PI option, please be aware that the structure and governance of the PD/PI leadership team as well as the knowledge, skills and experience of the individual PDs/PIs will be factored into the assessment of the overall scientific merit of the application. Multiple PDs/PIs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of required reports. For further information on multiple PDs/PIs, please see http://grants.nih.gov/grants/multi_pi.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current *NIH Grants Policy Statement*.

3. Other-Special Eligibility Criteria

Number of Applications. Applicants may submit more than one application, provided that each application is scientifically distinct.

Resubmissions. Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). Beginning with applications intended for the January 25, 2009 official submission due date, all original new applications (i.e., never submitted) and renewal applications are permitted only a single amendment (A1). See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html and NOT-OD-09-016. Original new and renewal applications that were submitted prior to January 25, 2009 are permitted two amendments (A1 and A2). For these “grandfathered” applications, NIH expects that any A2 will be submitted no later than January 7, 2011, and NIH will not accept A2 applications after that date.

Renewals. Exploratory/developmental grant support is for new projects only; renewal (formerly “competing continuation”) applications will not be accepted.

Section IV. Application and Submission Information

To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, use the “Apply for Grant Electronically” button in this FOA or link to http://www.grants.gov/Apply/ and follow the directions provided on that Web site.

Registration:

Appropriate registrations with Grants.gov and eRA Commons must be completed on or before the due date in order to successfully submit an application**. Several of the steps of the registration process could take four weeks or more.** Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered with both Grants.gov and the Commons. All registrations must be complete by the submission deadline for the application to be considered “on-time” (see 3.C.1 for more information about on-time submission).

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/applicants/get_registered.jsp) and
- eRA Commons (http://era.nih.gov/ElectronicReceipt/preparing.htm)

PDs/PIs should work with their institutions/organizations to make sure they are registered in the NIH eRA Commons.

Several additional separate actions are required before an applicant can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov/Get Registered.

- Your organization will need to obtain a Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:
  Grants.gov Customer Support
  Contact Center Phone: 800-518-4726
  Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time
  Email support@grants.gov

2) Organizational/Institutional Registration in the eRA Commons

- To find out if an organization is already Commons-registered, see the "List of Grantee Organizations Registered in NIH eRA Commons."
- Direct questions regarding the Commons registration to:
  eRA Commons Help Desk
  Phone: 301-402-7469 or 866-504-9552 (Toll Free)
  TTY: 301-451-5939
  Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time
  Email commons@od.nih.gov

3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the *NIH eRA Commons System (COM) Users Guide*.

- The individual designated as the PD/PI on the application must also be registered in the NIH eRA Commons. It is not necessary for PDs/PIs to register with Grants.gov.
- The PD/PI must hold a PD/PI account in the Commons and must be affiliated with the applicant organization. This account cannot have any other role attached to it other than the PD/PI.
- This registration/affiliation must be done by the Authorized Organization Representative/Signing Official (AOR/SO) or their designee who is already registered in the Commons.
- Both the PD/PI and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Note: The registration process is not sequential. Applicants should begin the registration processes for both Grants.gov and eRA Commons as soon as their organization has obtained a DUNS number. Only one DUNS number is required and the same DUNS number must be referenced when completing Grants.gov registration, eRA Commons registration and the SF424 (R&R) forms.

1. Request Application Information

Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this

FOA through Grants.gov/Apply.

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA), although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact GrantsInfo -- Telephone 301-435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-5936.

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms for this FOA through Grants.gov/Apply and in accordance with the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/index.htm).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. There are fields within the SF424 (R&R) application components that, although not marked as mandatory, are required by NIH (e.g., the “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component must contain the PD/PI’s assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see “Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.”

The SF424 (R&R) application is comprised of data arranged in separate components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov/APPLY will include all applicable components, required and optional. A completed application in response to this FOA will include the following components:

Required Components:
SF424 (R&R) (Cover component)
Research & Related Project/Performance Site Locations
Research & Related Other Project Information
Research & Related Senior/Key Person
PHS398 Cover Page Supplement
PHS398 Research Plan
PHS398 Checklist
PHS398 Modular Budget or Research & Related Budget, as appropriate (See Section IV.6. regarding appropriate required budget component.)

Optional Components:
PHS398 Cover Letter File
Research & Related Subaward Budget Attachment(s) Form

Foreign Organizations (Non-domestic [non-U.S.] Entities)

NIH policies concerning grants to foreign (non-U.S.) organizations can be found in the NIH Grants Policy Statement at: http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600260.

Applications from Foreign organizations must:

- Request budgets in U.S. dollars;
- Prepare detailed budgets for all applications (that is, complete the Research & Related Budget component of the SF424 (R&R) application forms – not the PHS398 Modular Budget component)(see NOT-OD-06-096);
- Not include any charge-back of customs and import fees;

- Comply with the format specifications, which are based upon a standard U.S. paper size of 8.5" x 11" within each PDF;
- If appropriate, request funds for up to 8% Facilities and Administrative (F&A) costs (excluding equipment) (see NOT-OD-01-028, March 29, 2001);
- Comply with Federal/NIH policies on human subjects, animals, and biohazards; and
- Comply with Federal/NIH biosafety and biosecurity regulations (see Section VI.2., "Administrative and National Policy Requirements")

Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States (U.S.) or that augment existing U.S. resources.

SPECIAL INSTRUCTIONS

Applications with Multiple PDs/PIs

When multiple PDs/PIs are proposed, NIH requires one PD/PI to be designated as the "Contact" PI, who will be responsible for all communication between the PDs/PIs and the NIH, for assembling the application materials outlined below, and for coordinating progress reports for the project. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PDs/PIs, but has no other special roles or responsibilities within the project team beyond those mentioned above.

Information for the Contact PD/PI should be entered on the SF424 (R&R) Cover component. All other PDs/PIs should be listed in the Research & Related Senior/Key Person component and assigned the project role of "PD/PI." Please remember that all PDs/PIs must be registered in the eRA Commons prior to application submission**. The Commons ID of each PD/PI must be included in the "Credential" field of the Research & Related Senior/Key Person component. Failure to include this data field will cause the application to be rejected.**

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, the section of the Research Plan entitled "Multiple PD/PI Leadership Plan", must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, and should include communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award (NoA).

Applications Involving a Single Institution

When all PDs/PIs are within a single institution, follow the instructions contained in the SF424 (R&R) Application Guide.

Applications Involving Multiple Institutions

When multiple institutions are involved, one institution must be designated as the prime institution and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution. When submitting a detailed budget, the prime institution should submit its budget using the Research & Related Budget component. All other institutions should have their individual budgets attached separately to the Research & Related Subaward Budget Attachment(s) Form. See Section 4.8 of the SF424 (R&R) Application Guide for further instruction regarding the use of the subaward budget form.

When submitting a modular budget, the prime institution completes the PHS398 Modular Budget component only. Information concerning the consortium/subcontract budget is provided in the budget justification. Separate budgets for each consortium/subcontract grantee are not required when using the Modular budget format. See Section 5.4 of the Application Guide for further instruction regarding the use of the PHS398 Modular Budget component.

3. Submission Dates and Times

See Section IV.3.A for details.

3.A. Submission, Review, and Anticipated Start Dates

Opening Date: September 16, 2010 (Earliest date an application may be submitted to Grants.gov)
Application Due Date(s): Standard dates apply, please see
http://grants.nih.gov/grants/funding/submissionschedule.htm
AIDS Application Due Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS
Peer Review Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Council Review Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Earliest Anticipated Start Date(s): Standard dates apply, please see
http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward

3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity.

3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/Apply and follow Steps 1-4. Note: Applications must only be submitted electronically**. PAPER APPLICATIONS WILL NOT BE ACCEPTED.** All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

3.C. Application Processing

3.C.1 Submitting On-Time

Applications **may** be submitted on or after the opening date and **must** be successfully received by Grants.gov no later than **5:00 p.m. local time** (of the applicant institution/organization) on the application due date(s). (See Section IV.3.A. for all dates.) If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed. All applications must meet the following criteria to be considered “on-time”:

- All registrations must be complete prior to the submission deadline
- The application must receive a Grants.gov tracking number and timestamp (or eRA help desk ticket confirming a system issue preventing submission) by 5:00 p.m. local time on the submission deadline date.
- Any system identified errors/warnings must be corrected and the submission process completed within the “error correction window.”

Please visit http://era.nih.gov/electronicReceipt/app_help.htm for detailed information on what to do if Grants.gov or eRA system issues threaten your ability to submit on time.

Submission to Grants.gov is not the last step – applicants must follow their application through to the eRA Commons to check for errors and warnings and view their assembled application!

3.C.2 Two Day Window to Correct eRA Identified Errors / Warnings

IMPORTANT NOTE! NIH has eliminated the error correction window for due dates of January 25, 2011 and beyond. As of January 25, all corrections must be complete by the due date for an application to be considered on-time. See NOT-OD-10-123.

Once an application package has been successfully submitted through Grants.gov, NIH provides applicants a two day *error correction window* to correct any eRA identified errors or warnings before a final assembled application is created in the eRA Commons. The standard error correction window is two (2) business days, beginning the day after the submission deadline and excluding weekends and standard federal holidays. All errors must be corrected to successfully complete the submission process. Warnings will not prevent the application from completing the submission process.

Please note that the following caveats apply:

- Initial application submission must be "on-time."
- The AOR/institutions is expected to enforce that application changes made within the error correction window are restricted to those necessary to address system-identified errors/warnings. NIH may reject any application that includes additional changes.
- Proof of "on-time" submission (e.g., Grants.gov timestamp and tracking number) and description of all changes made within the window must be documented in the PHS 398 Cover Letter component of the application.

3.C.3 Viewing an Application in the eRA Commons

Once any eRA identified errors have been addressed and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the assembled application before it automatically moves forward to NIH for further processing.

- If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can "Reject" the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to "Reject" the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12 of the SF 424 (R&R) application guide, including the requirement for cover letters on late applications. The "Reject" feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.
- If the two-day window falls after the submission deadline, the AOR/SO will have the option to "Reject" the application if, **due to an eRA Commons or Grants.gov system issue,** the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn't transfer correctly during the submission process). The AOR/SO should first contact the eRA Commons Helpdesk to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.

- If the AOR/SO chooses to "Reject" the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the NIH late policy guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Incomplete applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the Commons. The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on the application status in the Commons.

The NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. However, the NIH will accept a resubmission application, but such application must include an Introduction addressing the critique from the previous review.

4. Intergovernmental Review

This initiative is not subject to *intergovernmental review*.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

Pre-Award Costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See the *NIH Grants Policy Statement*.

6. Other Submission Requirements

PD/PI Credential (e.g., Agency Login)

The NIH requires the PD/PI to fill in his/her Commons User ID in the "PROFILE – Project Director/Principal Investigator" section, "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component. The applicant organization must include its DUNS number in its Organization Profile in the eRA

Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see “Registration FAQs – Important Tips -- Electronic Submission of Grant Applications.”

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see “Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.”

PHS398 Research Plan Component Sections

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts, and with the following requirements for R21 applications:

- Introduction (required for a resubmission or revision application) is limited to 1 page.
- Specific Aims is limited to 1 page.
- Research Strategy, including tables, graphs, figures, diagrams, and charts, is limited to 6 pages. See Table of Page Limits.
- Preliminary data are not required but may be included if available.

Budget Component

U.S. applicants submitting an application with direct costs in each year of $250,000 or less (excluding consortium Facilities and Administrative [F&A] costs) must use the PHS398 Modular Budget component.

U.S. applicants requesting more than $250,000 in annual direct costs and all foreign applicants must complete and submit budget requests using the Research & Related Budget component.

R21 applications will use the modular as well as non-modular budget formats and "Just-in-Time" information concepts, with direct costs requested in $25,000 modules, up to the total direct costs limitation of $275,000 over an R21 two-year period. No more than $200,000 in direct costs will be allowed in any single year. All foreign applicants must complete and submit requests using the Research & Related Budget component.

Appendix Materials

Applicants **must** follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (See http://grants.nih.gov/grants/funding/424/index.htm). Also see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html.

Do not use the Appendix to circumvent the page limitations. An application that does not comply with the required page limitations may be delayed in the review process.

Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this should be explained in the Resource Sharing section of the application (see http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm).

(a) *Data Sharing Plan*: Not Applicable

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources, or state appropriate reasons why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and NIH Guide NOT-OD-04-042.

(c) *Genome-Wide Association Studies (GWAS):* Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (e.g., blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (go to NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/.)

Foreign Applications (Non-domestic (non-U.S.) Entity)

Indicate how the proposed project has specific relevance to the mission and objectives of the NIH/IC and has the potential for significantly advancing the health sciences in the United States.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Review Process

Applications submitted for this funding opportunity will be assigned to the ICs on the basis of established Public Health Service (PHS) referral guidelines.

Applications that are complete will be evaluated for scientific and technical merit by (an) appropriate scientific review group(s) in accordance with NIH peer review procedures (http://grants1.nih.gov/grants/peer/) using the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a rating;
- Receive a written critique; and
- Receive a second level of review by the appropriate national advisory council or board.

The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will focus their evaluation on the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be

included if available.

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items**.

Protections for Human Subjects. For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information, see http://grants.nih.gov/grants/olaw/VAChecklist.pdf.

Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications. When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications. Renewals are not allowed for this FOA.

Revision Applications. When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations. As applicable for the FOA or submitted application, reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agents Research. Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html); and 3) Genome Wide Association Studies (GWAS) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html).

Budget and Period Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Selection Process

Applications submitted in response to this funding opportunity will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

Not Applicable

Section VI. Award Administration Information

---

1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his/her Summary Statement (written critique) via the NIH eRA Commons.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the *NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General*.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Section IV.5., “Funding Restrictions.”

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and

Conditions for Specific Types of Grants, Grantees, and Activities.

3. Reporting

When multiple years are involved, awardees will be required to submit the Non-Competing Grant Progress Report (PHS 2590) annually and financial statements as required in the *NIH Grants Policy Statement*.

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research (program), peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Paul A Cotton, PhD, RD
Program Director, Office of Extramural Activities
National Institute of Nursing Research, NIH
6701 Democracy Blvd., Suite 710
One Democracy Plaza
Bethesda, MD 20892-4870
Telephone: (301) 402-6423
Fax: 301-451-5647
Email: cottonp@mail.nih.gov

Dr. Charlotte Pratt
Program Director
Division of Cardiovascular Sciences
Prevention and Population Sciences Program
Clinical Application and Prevention Branch
National Heart, Lung and Blood Institute, NIH
6701 Rockledge Drive, Suite 10118, MSC 7936
Bethesda, Md 20892-7936
Telephone: (301) 435-0382
Fax: (301) 480-5158
E-mail: prattc@nhlbi.nih.gov

Dr. Linda Nebeling
Chief, Health Promotion Research Branch
Behavioral Research Program
Division of Cancer Control and Population Sciences
National Cancer Institute, NIH
6130 Executive Blvd., Room 4060
Rockville, MD 20892
Telephone: (301) 435-2841
Fax: (301) 435-7547
E-mail: nebelinl@mail.nih.gov

2. Peer Review Contacts:

Not Applicable

3. Financial or Grants Management Contacts:

Randi Freundlich
Grants Management Specialist, Office of Grants Management
National Institute of Nursing Research, NIH
6701 Democracy Blvd., Suite 710
One Democracy Plaza
Bethesda, MD 20892-4870
Telephone: (301) 594-5974
Fax: (301) 402-4502
Email: Freundlichr@mail.nih.gov

Gayle T. Jones
Grants Management Specialist
Division of Cardiovascular Sciences
National Heart, Lung and Blood Institute, NIH
6701 Rockledge Drive, Suite 7148, MSC 7926
Bethesda, Md 20892-7936
Telephone: (301) 435-0140
Fax: (301) 451-5462
E-mail: jonesgt@nhlbi.nih.gov

Carol A. Perry
Branch Chief, Branch D
Cancer Control and Population Sciences Branch
Office of Grants Administration
National Cancer Institute, NIH
6120 Executive Blvd., Suite 243
Bethesda, MD 20892-4870 (for regular mail)
Rockville, MD 20852 (for hand delivered mail)
Telephone: (301) 493-7205
Fax: (301) 496-8601/ 301-480-3691
Email: perryc@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:
Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection:
Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to

be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Data and Safety Monitoring Plan:
Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH Policy for Data and Safety Monitoring," *NIH Guide for Grants and Contracts*, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:
Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing). Investigators should seek guidance from their institutions, on issues related to institutional policies and local institutional review board (IRB) rules, as well as local, State and Federal laws and regulations, including the Privacy Rule.

Policy for Genome-Wide Association Studies (GWAS):
NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088. For additional information, see http://grants.nih.gov/grants/gwas/.

Sharing of Model Organisms:
NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh-Dole Act (see the *NIH Grants Policy Statement*. Beginning October 1, 2004, all investigators submitting an NIH application or contract proposal are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are: (1) first produced in a project that is supported in whole or in part with Federal funds; and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use

of data collected under this award.

Inclusion of Women And Minorities in Clinical Research:
It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the SF424 (R&R) application; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Required Education on the Protection of Human Subject Participants:
NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Human Embryonic Stem Cells (hESC):
Criteria for Federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-116.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (http://escr.nih.gov/). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research.

NIH Public Access Policy Requirement:
In accordance with the NIH Public Access Policy, *investigators funded by the NIH must submit or have submitted for them to the National Library of Medicine's PubMed Central* (see http://www.pubmedcentral.nih.gov/), *an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.* The NIH Public Access Policy is available at (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html). For more information, see the Public Access webpage at http://publicaccess.nih.gov/.

Standards for Privacy of Individually Identifiable Health Information:
The Department of Health and Human Services (HHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs

the protection of individually identifiable health information, and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs in NIH Grant Applications or Appendices:
All applications and proposals for NIH funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, Internet addresses (URLs) or PubMed Central (PMC) submission identification numbers must be used for publicly accessible on-line journal articles. Publicly accessible on-line journal articles or PMC articles/manuscripts accepted for publication that are directly relevant to the project may be included **only** as **URLs** or **PMC submission identification numbers** accompanying the full reference in either the Bibliography & References Cited section, the Progress Report Publication List section, or the Biographical Sketch section of the NIH grant application. A URL or PMC submission identification number citation may be repeated in each of these sections as appropriate. There is no limit to the number of URLs or PMC submission identification numbers that can be cited.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

Authority and Regulations:
This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:
NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: http://www.lrp.nih.gov/.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Office of Extramural Research (OER)

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Department of Health and Human Services (HHS)

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.